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No. 01-660

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In The

# Supreme Court of the United States

ELI LILLY AND COMPANY,

*Petitioner,*

v.

BARR LABORATORIES, INC.,
AND
APOTEX, INC. and BERNARD C. SHERMAN,
AND
GENEVA PHARMACEUTICALS, INC.,
AND
INTERPHARM, INC.,

*Respondents.*

**On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit**

## REPLY BRIEF

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## REPLY BRIEF

The rule of law announced by the Federal Circuit effectively requires a patentee to forfeit an *entire basic patent*, not just any "unjustified" extended period of exclusivity, for no other reason, and based on no other facts, than that the Patent and Trademark Office ("PTO") issued that patent after the PTO had issued a separate patent on a concededly *nonobvious*, patentably distinct, follow-on invention. This facially illogical rule does violence to the statutory scheme and will have profoundly adverse consequences not just for untold numbers of basic patents in "reverse order of issuance" cases, but for the patent system as a whole, as Lilly's amici emphasize.

1.a. Barr does not dispute that Lilly's application to patent its improvement invention (Stark) referred explicitly to its earlier-discovered basic invention (Molloy) as "prior art." Nor does Barr contest that Stark was correctly found by the PTO to be a nonobvious improvement over Molloy, and that Section 103 therefore provides that the two inventions are "patentably distinct." As Barr acknowledges, not a single case in the century-old, 500-plus-case jurisprudence on obviousness-type double patenting has ever applied the nonstatutory doctrine to invalidate a "prior art" basic invention in light of a later-discovered, later-filed, nonobvious improvement invention. Barr Brief in Opposition ("Barr Opp.") at 1, 11-13.[1]

For this reason, and because the only common-sense way to test "obviousness" is to ask whether the *later* discovered and filed invention is nonobvious in light of the *earlier* discovered and filed invention, Lilly submits that its Stark and Molloy patents cannot, as a matter of law, be held to be "double patents." As Judge Newman aptly put it in dissent below, "[w]hatever effect the '549

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[1] Barr's citation of *In re Borg*, 392 F.2d 642 (C.C.P.A. 1968), is inapposite because it held that a later-filed invention (Borg) was "double patenting" in light of an earlier-filed invention (Zajac) that the PTO had *not* applied as prior art.

[Molloy] and Stark patents may have on each other, it is not 'double patenting.' " Pet. App. 43a.

Because it cannot deny that the Molloy and Stark inventions are patentably distinct under Section 103, Barr argues that "Section 103 determines whether the claimed invention is patentable over the statutory prior art," whereas "[t]he double patenting doctrine . . . determines whether the applicant is improperly extending its patent monopoly beyond the statutorily-prescribed term." Barr Opp. at 17. But this facile description is entirely circular. The judicial "double patenting" doctrine will find a patent monopoly extension to be "improper" *only* where it finds that two patents have issued for patentably *indistinct* inventions. Thus, the Federal Circuit has repeatedly stated that " 'as a matter of law the extension of protection objection is not necessarily controlling.' "[2]

In short, what matters in double patenting is not whether one patent's term extends beyond that of another, but whether the two patents cover patentably indistinct inventions. Here, because the Molloy and Stark inventions have a prior art relationship, the PTO correctly applied Section 103 and determined that the inventions are patentably distinct, and it therefore makes no sense to apply any additional, nonstatutory test of patentable distinctness.[3] And given that there is no finding, evidence,

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[2] *See In re Braat*, 937 F.2d 589, 594 (Fed. Cir. 1991) (citing *In re Borah*, 354 F.2d 1009, 1017 (C.C.P.A. 1966); *In re Stanley*, 214 F.2d 151 (C.C.P.A. 1954)).

[3] By contrast, for commonly owned inventions that do *not* have a prior art relationship, the judicial doctrine of double patenting (rather than Section 103) serves to determine patentable distinctness. *See* Pet. at 17-21. Contrary to Barr's claim, Barr Opp. at 16, *In re Bowers*, 359 F.2d 886 (C.C.P.A. 1966), actually confirms that the two tests are "mutually exclusive," whereby Section 103 determines patentable distinctness for earlier inventions that are in the statutory "prior art," and judicial double patenting does so for that subset of earlier or

or even *allegation* in the record of this case that " 'the delay in the issuing of the patent for the main [Molloy] invention [can] be charged to the laches or fraud of the patentee,' " Pet. at 22 (quoting *Thomson-Houston Elec. Co. v. Ohio Brass Co.*, 80 F. at 712, 724 (6th Cir. 1897) (Taft, J.)), both the Molloy and Stark inventions are entitled to separate patents with independent patent terms.

b. Nevertheless, even if the nonstatutory doctrine of obviousness-type double patenting applied here, it would hold that "the order of issuance should be disregarded in this special situation and the later issuing [basic] patent should be upheld if the improvement is patentably distinct from the [basic] invention." CHISUM ON PATENTS § 9.03[2][c] (2000) (citing cases). Double patenting cases, including those cited by Barr, focus on inventions made at around the same time, for which patents were sought contemporaneously, but in different applications. Barr Opp. at 17-19. In that context, they inquire whether the invention claimed in the *later-issued* patent is nonobvious in light of the invention claimed in the *earlier-issued* patent.

But as even Barr acknowledges, this inquiry is reversed " 'to prevent rejections for obviousness-type double patenting *when the applicants filed first for a basic invention and later for an improvement, but, through no fault of the applicants, the PTO decided the applications in reverse order of filing.*' " Barr Opp. at 19 (citing *In re Berg*, 140 F.3d 1428, 1432 (Fed. Cir. 1998)) (emphasis added). This common-sense approach, the so-called "two-way test" for double patenting, adheres to the patents' "order of discovery," examining whether the later-discovered improvement invention is nonobvious in light of the earlier-discovered basic invention, notwithstanding the fact that the patents on those inventions were issued by the PTO in reverse order of their filing. Thus, a Federal Circuit decision cited by Barr as an example of the two-

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contemporaneous inventions that are statutorily *carved out* of the prior art. *See* 359 F.2d at 889.

way test for double patenting holds that "when a later filed improvement patent issues before an earlier filed basic invention, a double patenting rejection is only proper against the claims to the basic invention if the improvement is not patentably distinct from the basic invention." *In re Braat*, 937 F.2d 589, 593 (Fed. Cir. 1991). Under that rule of law, Lilly clearly prevails in this case.

According to Barr and the Federal Circuit, however, this common-sense "two-way" test applies only when the PTO was "solely responsible" for the delay that caused the patent on the later-filed improvement invention to issue before the patent on the earlier, basic invention. Pet. App. 24a n.7; Barr Opp. at 19-21. And here the Federal Circuit determined that the PTO was not "solely responsible" for the issuance of the Stark improvement patent before the Molloy basic patent only because Lilly's claims on the basic invention "could have been presented earlier." Pet. App. 24a-25a n.7.

But, as Lilly's amici demonstrate, it will always, or virtually always, be possible to say that the claims in a basic patent "could have been presented earlier." Brief of Amicus Intellectual Prop. Owners Ass'n ("IPO Br.") at 5-6; Brief of Amicus Biotechnology Indus. Org. & Pharm. Research Mfrs. ("BIO Br.") at 13, 15. For example, while Lilly complied with all filing deadlines in prosecuting its Molloy claims, it certainly could have made some filings earlier. For the Federal Circuit now to require Lilly to forfeit entirely its valuable Molloy patent because its claims "could have been presented earlier" is akin to denying a petition for certiorari filed on the 90th day – while it was not untimely, it "could have been filed earlier." Indeed, no matter how blameworthy the PTO may be in a given case for the reverse order of issuance of basic and improvement patents, it will rarely if ever be *solely* responsible, since the patent holder could have taken some action "earlier." Thus, the Federal Circuit has announced a radical new standard that will inevitably result in the *a priori* denial of the full patent term for

otherwise patentable basic inventions in all "reverse order" cases. *See* IPO Br. at 5-6; BIO Br. at 13.

In sum, whether it erred in applying the nonstatutory double patenting test to two inventions found to be patentably distinct under Section 103, or in refusing to honor the common-sense principles behind the two-way test exception, the Federal Circuit held that Lilly's patent on its basic Molloy invention must be forfeited in its entirety based solely on the fact that it issued seven months after a patent on the nonobvious Stark improvement invention, and on the inevitable reality that the Molloy claims "could have been presented earlier." No other facts were thought to be relevant to the decision to invalidate Lilly's basic Prozac patent. However the rule of law from this decision is described, it is plainly wrong and demands review by this Court.

c. In an effort to provide an *ex post* justification for the Federal Circuit's harsh decision, Barr repeatedly asserts that Lilly "intentionally" and "strategically" delayed issuance of its basic Molloy patent. *See, e.g.*, Barr Opp. at 2-7, 12, 21, 23.

First, Barr's gravely serious charges are conspicuously lacking in supporting citations to the evidentiary record in this case. This is not surprising, given that there is no evidentiary record on Barr's charges. After all, the district court granted *summary judgment* for Lilly on Barr's double patenting defense, and Barr never even alleged, let alone proved, that Lilly had intentionally delayed the progress of its Molloy application or had otherwise engaged in dilatory conduct or prosecutorial laches. To the contrary, Lilly applied for a patent on its basic discovery in 1974, but did not obtain its Molloy patent in direct response to that application largely because *the PTO* determined that Lilly's initial application contained multiple innovations, and therefore was *required* to be broken up into multiple "divisional" applications. That decision by the PTO, not any action taken by Lilly, launched Lilly on a highly complicated, contentious 12-year application process, resulting in multiple

"basic" patents covering different aspects of its initial Prozac innovation. Pet. at 7-8.

Indeed, there was nothing whatsoever dilatory about Lilly's prosecution of the Molloy patent. Lilly conformed in *every* respect with *all* of the procedural requirements that governed the prosecution of its patents, including those governing timeliness,[4] and there has never been any claim to the contrary. Thus, Barr explains, "[t]he PTO promptly issued" the Molloy patent in 1986 in full view of Lilly's other related Prozac patents, yet it voiced no qualms about the 12-year period since Lilly's initial 1974 application. Nor did the district court raise a question about Lilly's good faith in prosecuting its Molloy patent.

Second, Barr does not and cannot contest the fact that the prosecution of patents relating to a pathbreaking innovation like Prozac will often last for a decade or more. Indeed, it makes no effort to distinguish cases with similar prosecution histories that were found to be wholly unproblematic. *See* Pet. at 8 nn.1-3. The patented claims at issue in those cases surely "could have been presented earlier," yet that was hardly a sufficient basis for invalidating those patents.

Finally, Barr fails to explain how Lilly's alleged "manipulation" of the issuance of its basic Molloy patent has any legal relevance to this case. The decision below is predicated on the existence of the Stark patent, which has never had any commercial value to Lilly and was disclaimed in its entirety during the pendency of this case. *See* Pet. at 10. Indeed, Lilly would have enjoyed precisely the same benefit of the alleged "strategic delay" had it never obtained the Stark patent. Thus, the decision below cannot intelligibly be attributed to any alleged "strategic delay."

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[4] *See, e.g.*, 35 U.S.C. § 120; *In re Henriksen*, 399 F.2d 253 (C.C.P.A. 1968).

2. Barr and Respondent Geneva Pharmaceuticals, Inc., understandably refuse to defend the manifestly irrational reasoning that because Lilly had previously disclaimed the Stark patent in its entirety it cannot now terminally disclaim Molloy. *See* Pet. App. 23a; Pet. at 27-30. Rather, Respondents argue that "[i]t is simply too late" for Lilly even to raise the issue of its right under Section 253 to terminally disclaim Molloy. Barr Opp. at 7; Geneva Brief in Opposition ("Geneva Opp.") at 1. At the root of this argument is the fact that Respondents "argued for six years that the [Molloy] patent was invalid for double patenting and during that whole time, Lilly never filed a terminal disclaimer." Barr Opp. at 25; *see* Geneva Opp. at 2-3. Thus, Respondents contend that when they raised their double patenting defense to Lilly's infringement claim, Lilly was put to an election: either Lilly could file a terminal disclaimer then and there (and thus surrender on the merits of the double patenting defense) or it could dispute the merits of the double patenting defense (and thus waive its statutory right to later terminally disclaim any portion of the Molloy patent found to constitute an unjustified timewise extension).

Respondents' contention is absurd on its face. Nothing in the language of Section 253, or in logic, precludes a post-judgment terminal disclaimer or otherwise places such a purposeless temporal constraint on a patent holder's critically important right to "*overcome a rejection* based on double patenting." *In re Longi*, 759 F.2d 887, 894 (Fed. Cir. 1985) (emphasis added). To the contrary, the language of both the statute and the cases applying it makes clear that a patent holder need not terminally disclaim his valuable patent rights until his patent has been rejected or invalidated for double patenting. *See, e.g., Quad Envtl. Tech. Corp. v. Union Sanitary Dist.*, 946 F.2d 870, 874 (Fed. Cir. 1991) ("In legal principle, the filing of a terminal disclaimer simply serves the statutory function of *removing the rejection of double patenting* . . . . ") (emphasis added); *In re Goodman*, 11 F.3d 1046, 1052 (Fed. Cir. 1993) ("patentee may *overcome* the double patenting

rejection by filing a terminal disclaimer"). Not surprisingly, neither Barr nor Geneva offers a single case supporting their reading of the statute.

Indeed, the decision below itself refutes Respondents' contention. The court said nothing at all about timeliness, and its ruling necessarily implied that Lilly *would* have been able to terminally disclaim Molloy *if* it had not previously disclaimed all of Stark. As Lilly's amici stress, the Federal Circuit's ruling on Section 253 has sweeping implications and is independently worthy of this Courts' review. IPO Br. at 7-8.[5]

3. In an effort to support its claim that this case is not "important," Barr erroneously states that Lilly argued in the court below that the issue in this case had never before arisen. To the contrary, Lilly argued below, as here, that no court has ever invalidated a basic "prior art" patent as obvious in light of a later-discovered, later-filed, but earlier-issued patent on a patentably distinct improvement invention. Thus, this case is unprecedented only because of the radical *rule of law* it announces, not because of the commonplace facts it addresses.

Noting that the patent law was amended in 1995 to measure a patent term not as 17 years from the date of

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[5] As anticipated, Pet. at 28 n.10, Respondents labor mightily to mislead this Court into the false belief that the Federal Circuit's *actual* decision preemptively truncating Lilly's (and countless others') enormously valuable terminal disclaimer rights under Section 253 somehow should not concern this Court because Respondents made another double patenting argument below (relating to Lilly's "Holland" patent for hypertension) that, *if* it had been accepted by the Federal Circuit, would not have given rise to any terminal disclaimer issue. But the Federal Circuit carefully and deliberately did *not* accept Respondents' Holland-based double patenting argument, and the Stark-based double patenting argument that the Federal Circuit *actually did* accept *actually did* give rise to the Court of Appeals' profoundly important, clearly wrong, and plainly certworthy terminal disclaimer ruling.

issuance, but rather as 20 years from the date of application, 35 U.S.C. § 154, Barr argues that it is "exceedingly unlikely" that the issue in this case will ever arise again. Barr Opp. at 13-14. It is true that the 1995 rule addresses the problem of "inordinate delays in the PTO," so that doctrines such as laches and inequitable conduct will likely be invoked less frequently. But this is not a laches case. This is a double patenting case, and the 1995 rule change has *nothing* at all to do with the determination of when two inventions are patentably distinct versus when there is "double patenting."

Nothing in the 1995 law obviated the need to determine whether two inventions are patentably distinct. Thus, as Lilly's amici emphasize, the Federal Circuit's decision will "effectively lead to a *per se* rule" in all future cases involving "reverse order of issuance," resulting in "the inappropriate invalidation of claims in distinct patents that *each* fully meet the requirements for patentability." BIO Br. at 16. This expansive *per se* rule will produce a number of harsh results that are wholly unaffected by the 1995 rule change.

First, the decision below will still invalidate the terminal portion of any basic patent that expires after a nonobvious improvement patent, even if the later expiration of the basic patent's term has nothing at all to do with laches or inexcusable delay on the part of the patentee.[6] Second, just as Lilly has lost its Molloy basic

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[6] The phenomenon of a basic patent lawfully expiring later than the patent on a later-discovered, nonobvious improvement invention will still exist for patents covered by the 1995 rule. For example, it will certainly be possible under the law for a patentee to apply for his basic patent up to twelve months after he applies for his improvement (and after he publicly discloses his basic invention as prior art to that improvement). In addition, under a 1999 amendment a basic patent may be given an extension on the normal 20-year term wherever, as in this case, the PTO has contributed to the delay in issuing that patent. See BIO Br. at 17 n.11.

patent even for that period during which Molloy merely overlaps Stark's term, the decision will require any "double patent" that has a disclaimed or disowned "twin" to be *completely invalidated* even though it presents no issue of "timewise extension" whatsoever. Third, the Federal Circuit's decision will require a finding of double patenting with respect to post-1995 basic patents in "reverse order of issuance" cases even if the basic invention's patent term will expire *before* that of the later-discovered, nonobvious improvement; the patentee will thus be precluded from selling or transferring either of its "double patents," thereby substantially reducing their commercial value. 37 C.F.R. § 1.321(c)(3) (2001).

Finally, of course, there are untold numbers of pre-1995 patents that will fall under the Federal Circuit's radical new theory of obviousness-type double patenting. That prospect alone will profoundly alter the landscape of patent-dependent, high-technology industries in this country for at least a decade to come. BIO Br. at 18-19.

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